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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/610,891	07/06/2000	James McArthur	40567	6712

7590

06/04/2002

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EXAMINER

DAVIS, NATALIE A

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 06/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/610,891

Applicant(s)

MCARTHUR ET AL.

Examiner

Natalie A. Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's amendment filed 28 February 2002 (Paper No: 10) is acknowledged. Accordingly, claim 23 is amended, claims 23-34 are pending and under examination.

Response to Arguments

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112 1st Maintained

1. Rejection of claims 23-34 under 35 U.S.C. 112, first paragraph is maintained for reasons set forth in the previous office action. The traversal is on the grounds that the specification teaches how to make and use the cells, constructs, and other materials of interest and teaches how to render a cell proliferation incompetent. Applicant's arguments have been considered but are not persuasive. As indicated in the previous office action, the specification does not provide any guidance or exemplify that the vaccine is able to protect from the development or recurrence of cancer. In addition, the art (Spitler) teaches the unpredictability of cancer vaccines in the treatment of cancer (paragraph 7). In view of the lacking of guidance and working examples and the unpredictability in the art, one of ordinary skill in the art would require undue experimentation to practice the invention as claimed.

Claim Rejections - 35 USC § 102 Maintained

2. Rejection of claims 23-34 over Dranoff, et al. (6,637, 483) under 35 U.S.C. 102(b) and the rejection of claims 23-29 and 30-34 over Hiserdodt, et al. (WO 98/04282, 1998) is maintained for reasons set forth in the previous office action. The traversal is on the grounds that the instant invention is drawn to a tumor associated antigens which alone do not stimulate a humoral response, but do stimulate a response when administered with a proliferation-incompetent cell in the presence of a cytokine and Dranoff does not teach the claimed invention. Likewise, applicants argue that Hiserdodt's invention relates to tumor antigens that are

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recognized by the host and the tumor cells are poorly immunogenic, which is different from one that is not immunogenic but for the simultaneous administration of proliferation-incompetent cells and cytokines. Applicant's arguments have been considered but are not persuasive because the specification discloses tumor antigens as those which may not be or are weakly immunogenic (p. 24, line 19). Furthermore tumor cells that are poorly immunogenic may not be immunogenic enough to stimulate a humoral response. Accordingly, Drandoff and Hiserdodt teach the tumor-associated antigen as claimed and anticipate the invention as claimed.

New Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 23-34 are rejected under 35 U.S.C. 112, first paragraph. The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing.

Vas-Cath Inc. v. Mahurkar (CA FC) 19 USPQ2d 1111 (6/7/1991) clearly states that "written description" of invention required by first paragraph of 35 U.S.C. 112 is separate and distinct from that paragraph's requirement of enabling disclosure, since description must do more than merely provide explanation of how to "make and use" invention; applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed. An applicant shows possession by describing the claimed invention with all its limitations using such descriptive means as words, structures, diagrams, and formulas. Also, description of an actual reduction to practice, or by showing the invention was "ready for patenting," or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention at the time of filing.

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The specification, while containing a written description for a tumor antigen, does not reasonably provide written description for a tumor-associated antigens of molecular weight consisting of 250, 160, 150, 130, 105, 60, 32, 31, 27, 26, 14, and 12 kD. The disclosure does not indicate that applicant had possession of tumor-associated antigen consisting of said molecular weights. The specification discloses that the tumor-associated antigen may be obtained from tumor cells, such as prostate (p. 66), but does not disclose the isolation of and assaying of tumor-associated antigens consisting of said molecular weights. There is no actual reduction to practice, sufficient descriptive information, such as definitive structural features, which are critical to activity, or complete detailed description of the antigen indicating that the claimed tumor-associated antigens were indeed isolated, produced, and assayed for the uses disclosed. Thus, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the claimed antigens. The rejection may be overcome if the claims were to indicate the tumor-associated antigens of said molecular weights derived from prostate or some language supported by the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa PhD can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie Davis, PhD
May 29, 2002


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600